

Statistical Evaluation of the Performance of the
TEM (Transmission Electron Microscopy) Clearance Procedure

Price Associates, Washington, DC

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**STATISTICAL EVALUATION OF THE PERFORMANCE
OF THE TEM CLEARANCE PROCEDURE**

by

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FOREWORD

Today's rapidly developing and changing technologies and industrial products and practices frequently carry with them the increased generation of materials that, if improperly dealt with, can threaten both public health and the environment. The U.S. Environmental Protection Agency is charged by Congress with protecting the Nation's land, air, and water systems. Under a mandate of national environmental laws, the agency strives to formulate and implement actions leading to a compatible balance between human activities and the ability of natural systems to support and nurture life. These laws direct the EPA to perform research to define our environmental problems, measure the impacts, and search for solutions.

The Risk Reduction Engineering Laboratory is responsible for planning, implementation, and management of research, development, and demonstration programs to provide an authoritative, defensible engineering basis in support of the policies, programs, and regulations of the EPA with respect to drinking water, wastewater, pesticides, toxic substances, solid and hazardous wastes, and Superfund-related activities. This publication is one of the products of that research and provides a vital communication link between the researcher and the user community.

During asbestos abatement, the work site is isolated by containment barriers to prevent release of asbestos fibers into the rest of the building or into the outdoor air. As required under the Asbestos Hazard Emergency Response Act of 1986, EPA has proposed a rule that includes a procedure for determining when the abatement site is sufficiently clean for the containment barriers to be removed. This study describes an analysis of the statistical performance of the transmission electron microscopy (TEM) clearance procedure.

E. Timothy Oppelt, Director
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ABSTRACT

As required under the Asbestos Hazard Emergency Response Act of 1986 (AHERA), EPA has proposed a rule that includes a three-step procedure for determining when an asbestos abatement site is sufficiently clean for the containment barriers to be removed. The procedure involves collecting air samples inside and outside the work site and analyzing them by Transmission Electron Microscopy (TEM).

EPA has evaluated the performance characteristics of the three-step clearance procedure under a variety of conditions. This study extends the analysis by examining:

- o the performance of the clearance procedure under the assumption of a lognormal instead of a negative binomial for the statistical distribution of asbestos fiber concentrations;
- o statistical tests other than the Z-test to compare airborne asbestos concentrations inside the work site with those outside the work site;
- o the effect of varying sampling volumes as permitted under the rule; and
- o changes in the TEM protocol concerning fiber length and aspect ratio.

Performance is measured by the false positive and false negative error rates. A false positive occurs when the site fails the test even though the inside concentration is no greater than the outside concentration. A false negative occurs when a site with inside concentration higher than outside passes. The error rates were estimated by computer simulation.

The results of the study lead to the following recommendations:

- o The "true" statistical distribution of airborne asbestos measurements is unknown and is likely to vary from situation to situation. Any evaluation of the clearance procedure should include a sensitivity analysis to ensure that the procedure is robust to changes in the distribution. The negative binomial distribution should be included in the analysis, because, relative to the lognormal, it is a "worst case" that indicates higher false negative rates. Misleadingly low false negative rates may be obtained if the evaluation is based only on the lognormal distribution.

- o The Z-test should be retained in the rule. For the range of conditions considered, the Z-test has lower false negative rates than the t-test and Wilcoxon test and lower false positive rates than the Poisson test.
- o To reduce the false negative error rate at low airborne asbestos concentrations, the minimum air volume permitted under the rule should be increased, or alternatively, the initial screening test should be restricted to air volumes that are within or exceed the recommended range. (This requirement was incorporated into the final rule.)
- o Data need to be collected and analyzed to determine the effect of the new TEM protocol, which restricts fiber counts to structures longer than $0.5\mu\text{m}$ and with a 5:1 aspect ratio or greater. The effect can be quantified by a combination of designed laboratory experiments, analysis of clearance data, and computer simulation.

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SECTION 1

INTRODUCTION

As required under the Asbestos Hazard Emergency Response Act of 1986 (AHERA), EPA has proposed a rule regarding inspections, abatement, and management of asbestos-containing material in schools (April 30, 1987; 52 FR 15820). The proposed rule includes a three-step procedure for determining when an asbestos abatement site is sufficiently clean for the containment barriers to be removed. The procedure involves collecting air samples inside and outside the work site and analyzing them by Transmission Electron Microscopy (TEM). An initial screening of the inside samples allows the site to pass if asbestos fiber counts are within the range commonly seen on blanks (filters through which no air has been drawn). If the inside samples do not pass the initial screening, blanks must be analyzed to check for filter and field contamination. If the blanks pass the contamination test, the inside samples are compared to the outside samples using a statistical test, the Z-test. The work site passes if the inside airborne asbestos concentrations are not statistically higher than the outside concentrations.

EPA has evaluated the performance characteristics of the three-step clearance procedure under a variety of conditions (Chesson and Price 1987) using a negative binomial distribution to describe the statistical distribution of asbestos fiber concentrations and the Z-test to perform the inside/outside comparisons. The purpose of the study described in this report is to extend the analysis by examining:

- o a lognormal instead of a negative binomial for the statistical distribution of asbestos fiber concentrations;
- o statistical tests other than the Z-test to compare airborne asbestos concentrations inside the work site with those outside the work site;
- o the effect of varying sampling volumes as permitted under the rule; and

- o changes in the TEM protocol concerning fiber length and aspect ratio (length:width).

Performance of the clearance procedure is measured by the false positive and false negative error rates (i.e., Type I and Type II statistical error rates). A false positive occurs when the site fails the test even though the true inside concentration is no greater than the true outside concentration. A false negative occurs when a site with inside concentration higher than outside passes. ("True" in this context refers to the actual underlying concentrations, not the mean of five measurements.) The error rates were estimated by computer simulation.

Conclusions and recommendations are given in Section 2. The clearance procedure is described in Section 3 and Section 4 details the methods used to evaluate performance. The results are stated in Section 5.

SECTION 2

CONCLUSIONS AND RECOMMENDATIONS

The main results of this evaluation of the proposed TEM clearance procedure are:

- o The false negative error rates (probability of passing the clearance test when airborne asbestos concentrations are higher inside the work site than outside the work site) are lower when the underlying statistical distribution of airborne asbestos concentrations follows a lognormal distribution than when it follows a negative binomial distribution.
- o Of the four inside/outside comparison tests (the Z-test, t-test, Poisson test, and Wilcoxon test) considered, the Poisson test has the lowest false negative error rates, but the highest false positive rates. The remaining three tests have comparable false positive error rates. The Wilcoxon test has the highest false negative error rate, followed by the t-test, and then the Z-test.
- o Sampling the minimum volume of air increases the false negative error rate, particularly at airborne asbestos concentrations less than 0.06 f/cm^3 . The short-term cost advantage of an increased probability of passing is countered in part by increased analytical costs. Conversely, sampling the maximum volume of air decreases the false negative error rate.
- o Counting only fibers longer than $0.5 \mu\text{m}$ and with an aspect ratio of 5:1 or greater may increase or decrease decision error rates depending on the effect on measurement precision and whether there is a differential effect on measurements of airborne asbestos concentrations inside and outside the work site.

The results lead to the following conclusions and recommendations:

- o The "true" statistical distribution of airborne asbestos measurements is unknown and is likely to vary from situation to situation. Any evaluation of the clearance procedure should include a sensitivity analysis to ensure that the procedure is robust to changes in the distribution. The negative binomial distribution should be included in the analysis, because, relative to the lognormal, it is a "worst case" which indicates higher false negative rates. Misleadingly low false negative rates may be obtained if the evaluation is based only on the lognormal distribution.
- o The Z-test should be retained in the rule. For the range of conditions considered, the Z-test has lower false positive error rates than the Poisson test and lower false negative rates than the t-test and Wilcoxon test.
- o To reduce the false negative error rate at low airborne asbestos concentrations, the minimum air volume permitted under the rule should be increased, or alternatively, the initial screening test should be restricted to air volumes that are within or exceed the recommended range.
- o Data need to be collected and analyzed to determine the effect of the new TEM protocol which restricts fiber counts to structures longer than $0.5\mu\text{m}$ and with a 5:1 aspect ratio or greater. Effects on precision should be determined from a designed laboratory experiment. Fiber size information (fiber length and width) from actual clearance samples should be analyzed to compare airborne asbestos concentrations estimated with and without the restrictions on fiber dimension. The sensitivity of the clearance procedure to these effects can be determined by methods similar to those used in this study.

SECTION 3

CLEARANCE PROCEDURE

The clearance procedure as stated in the proposed rule is illustrated by the flow diagram in Figure 1. After the work site has passed a thorough visual inspection, a minimum of five air samples must be collected inside the work site and a minimum of five air samples outside the work site. All samples are collected simultaneously. Three blanks are also required. One blank consists of a filter in an unopened cassette. The remaining two blanks are opened for less than 30 seconds; one within the work site, the other outside the work site where the air samples are being collected. The blanks are intended to check for asbestos contamination from sources other than the air being sampled. Contamination could occur during filter manufacture, handling in the field, transportation of the samples, and analysis in the laboratory.

The volume of air sampled must be between a specified maximum and minimum dependent on filter size, and must be such that the minimum non-zero airborne asbestos concentration (i.e., the value obtained when only one fiber is observed under the microscope) is no more than 0.005 fibers/cm³. This quantity is referred to as the "analytical sensitivity" in the proposed rule. The formula for calculating the analytical sensitivity is given in Appendix A. The volume of air sampled and the area of the filter examined under the microscope can be adjusted within specified limits to achieve the required analytical sensitivity of 0.005 fibers/cm³ or less. Increasing the volume or increasing the area will decrease the analytical sensitivity and thereby increase the precision of the estimates of concentration.

The samples are analyzed by TEM according to the protocol stated in the rule. The formula for calculating fiber concentration is given in Appendix A. The asbestos fiber concentration per square millimeter of filter area is calculated by dividing the number of fibers counted by the area of filter examined. (The area examined is the number of grid openings examined multiplied by the area of one grid opening.) The airborne asbestos concentration in fibers/cm³ is estimated by multiplying the fiber concentration per mm² by the effective area of the filter and dividing by the volume of air collected.

The five inside samples are analyzed first. If the mean fiber concentration per square millimeter of filter is less than

70 then the asbestos levels are considered to be indistinguishable from contamination levels unrelated to the air being sampled and the work site passes the clearance test. When 10 grid openings are examined and each grid opening is 0.0057mm^2 , 70 fibers/ mm^2 corresponds to approximately 4 asbestos fibers. In this case if the five inside samples average less than 4 fibers counted per sample, the work site passes and no further analysis is required.

If the inside samples do not pass the initial contamination test, the proposed rule requires that the three blanks be analyzed. If the average concentration of the three blanks exceeds 70 fibers/ mm^2 the source of contamination must be identified and corrected and a new set of air samples collected.

If the three blanks do not exceed 70 fibers/ mm^2 , the outside samples are analyzed and compared to the inside samples using the Z-test, a statistical test that determines whether the inside airborne asbestos concentration is significantly higher than the outside concentration. If the samples pass the Z-test, the work site passes the clearance test. If the samples do not pass the Z-test the site must be recleaned, new air samples collected, and the clearance testing procedure repeated.

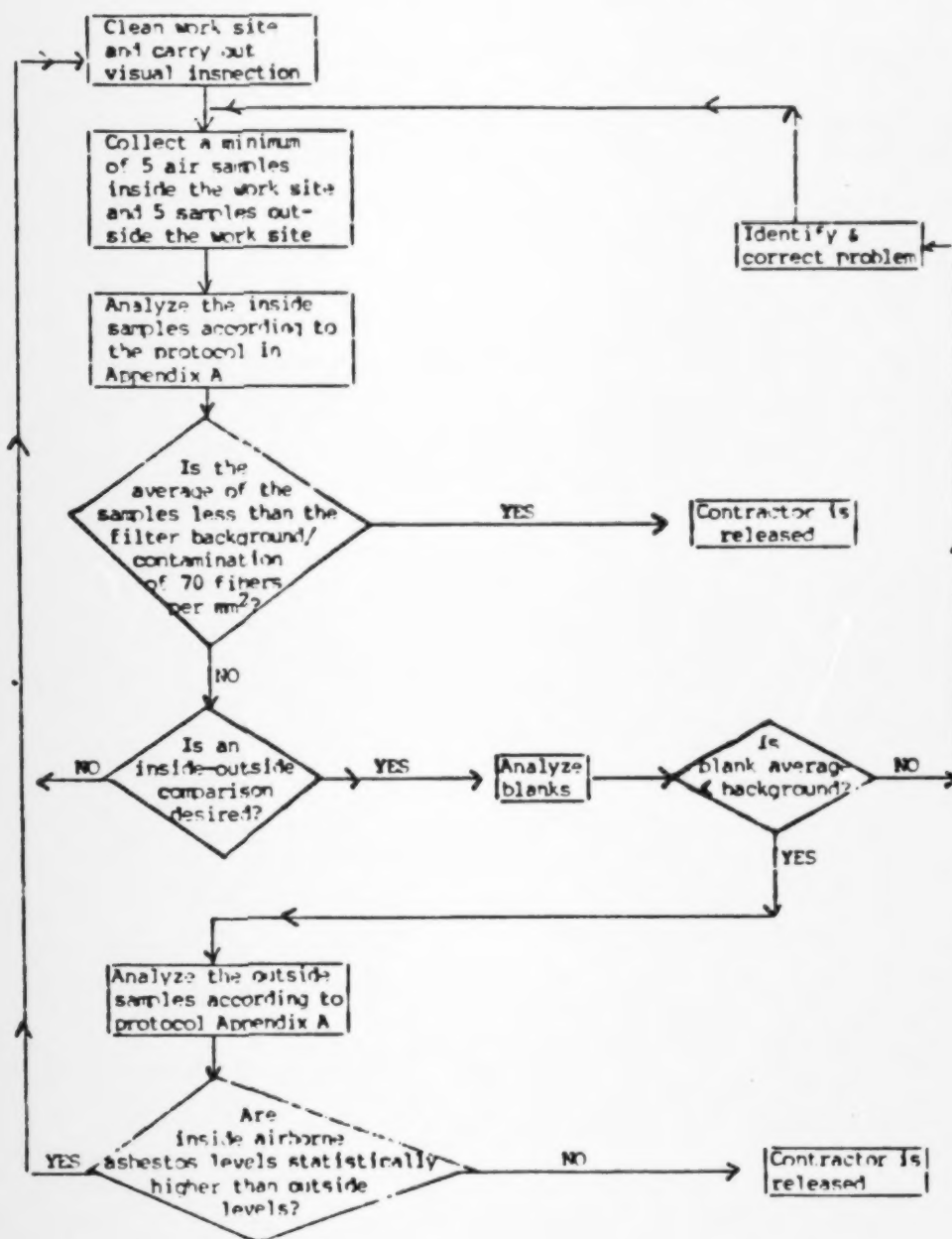


Figure 1. The three-step clearance procedure as proposed in the Federal Register (52 FR 15820).

SECTION 4

METHODS

GENERAL APPROACH

The approach is similar to that used for previous evaluations of the TEM clearance procedure using Monte Carlo simulation techniques (Chesson and Price 1987). A statistical model is developed to describe the distribution of asbestos fibers in the air samples. Samples are generated by computer according to the model and subjected to the series of tests specified in the clearance procedure. The process is replicated a large number of times (500) under a variety of conditions. False positive and false negative error rates are estimated by the proportion of passes and failures.

Statistical Model

The number of asbestos fibers counted on a filter during microscopic analysis depends on the level of filter contamination, the concentration of asbestos fibers in the air, the volume of air collected, and the proportion of filter examined. Let X represent the number of fibers on the portion of filter examined that were collected from the air and let C represent the number of fibers from filter contamination. Then $Y = X + C$ is the total number of fibers counted. If c_s denotes the airborne asbestos concentration in fibers/cm³, then $m_s = c_s * V / (A/a)$ is the expected value of X , where A is the effective area of the filter, a is the area that is examined under the microscope, and V is the volume of air collected. The expected value of C is $m_b = c_b * a$, where c_b is the contamination level on blank filters (in fibers/mm²). The expected value of Y is therefore $m_s + m_b$.

To evaluate the performance of the clearance test it is necessary to describe the statistical distribution of X and C . The negative binomial distribution has been used in previous evaluations because it is a discrete distribution which, by varying one or both of its two parameters, provides a good fit to a variety of empirical data. The lognormal distribution has also been used to describe airborne asbestos concentrations (Chesson et al 1985). In the current study the performance of the clearance procedure under the assumption of a lognormal

distribution is compared with its performance under the assumption of a negative binomial distribution.

The inside samples are denoted by $Y_{Ij} = X_{Ij} + C_{Ij}$, $j = 1, \dots, n_I$ where $n_I = 5$ in this case. The X_{Ij} and the C_{Ij} are each assumed to be independently and identically distributed with means m_I and m_{bI} respectively. Similarly the outside samples are denoted by $Y_{Oj} = X_{Oj} + C_{Oj}$, $j=1, n_O$, where the X_{Oj} and C_{Oj} are independent observations with means m_O and m_{bO} respectively.

This model forms the basis for the computer simulation program described below.

Simulation Program

The computer simulation mimics the clearance procedure (Figure 2). Samples are drawn from the appropriate probability distribution and subjected to the same series of tests that would be applied to real data.

The program generates separate cumulative probability distribution functions for the number of fibers present on a filter due to filter contamination, inside airborne asbestos concentration, and outside airborne concentration. Each inside and outside fiber count is generated by adding a random value from the filter contamination distribution to a random value from the inside or outside concentration distribution. Fiber counts for blanks are generated by drawing a random value from the filter contamination distribution. Fiber counts are converted to filter concentrations (fibers/mm²) and airborne asbestos concentrations (fibers/cm³) using the formula in Appendix A. A zero fiber count results in 0 f/mm² and 0 f/cm³.

Fiber counts for the 5 inside samples are generated first, converted to fibers/mm² and subjected to the initial screening test. If they pass the test the program records the fact and stops at that point. If they fail the initial screening test, fiber counts are generated for the 3 blank filters, converted to fibers/mm², and subjected to the blank contamination test. If they fail, the program stops. (For the evaluations performed in this report it is sufficient to count this situation as a failure. When a more complete evaluation involving the expected number of analyses is required, an additional cycle involving a new set of samples is included in the calculation.) If they pass, the fiber counts for the 5 outside samples are generated, fiber counts are converted to fibers/cm³, and subjected to the Z-test. (As required by the AHERA rule, zero fiber concentrations are set at the analytical sensitivity before applying the Z-test.) The result (pass or fail) is recorded.

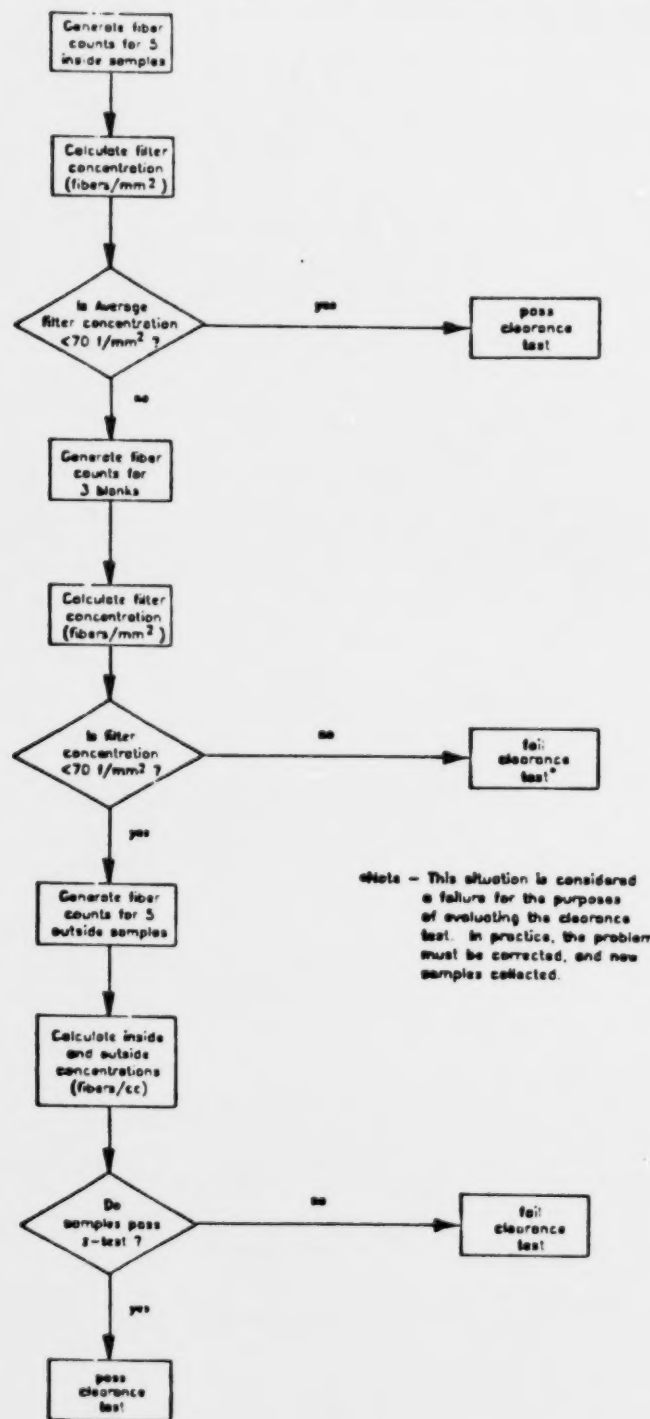


Figure 2. Flow chart of the steps in the simulation program.

This entire procedure is replicated 500 times and the proportion of replicates which pass the clearance test is used to estimate the probability of passing. With 500 replicates the width of an approximate 95% confidence interval for the estimated proportion is less than 0.06 when the true proportion is 0.1, and less than 0.09 when the true proportion is 0.5.

SPECIFIC ANALYSES

Underlying Distribution

Multiple air samples collected at a single location at the same time will not yield identical estimates of airborne asbestos concentration. Different estimates are obtained because they are based on different samples of air which are then subjected to a series of procedures (selection of the portion of the filter to prepare, selection of grid square openings to examine, etc.) that introduce additional variability. The statistical probability distribution of estimated airborne asbestos concentrations describes the range of possible values and their probability of occurrence at a given location. This distribution is used in the evaluation of the clearance procedure.

Distributions of estimated airborne asbestos concentration are typically skewed to the right and their variance tends to increase with their mean. Both the negative binomial and lognormal distributions have these properties and have been suggested as descriptions of estimated airborne asbestos concentrations. The lognormal distribution was used as the basis for designing the t-test for clearance (Chesson et al 1985) and its subsequent modification, the Z-test (Hatfield 1986). EPA's Office of Research and Development (ORD) found that the lognormal was a satisfactory description (no statistically significant difference at the 5% level) of all but one of 13 sets of airborne asbestos measurements taken after asbestos removal (C. Frebis, ORD, personal communication 1987). The negative binomial distribution was fitted to nine of these data sets (fiber counts were unavailable for one data set and the sample sizes were too small in the remaining three) and gave a satisfactory fit in 8 of the cases. The exception was the same data set that did not fit the lognormal distribution. This result is not surprising since the maximum sample size is 18. Larger sample sizes are needed to provide a high probability of distinguishing between the two similarly-shaped distributions.

At low airborne asbestos concentrations, such as those expected in a clearance situation, the distribution of the estimated concentrations is discrete since it is calculated from a small number of asbestos fibers. Therefore a discrete distribution such as the negative binomial is particularly suited to this application. The lognormal distribution has been used

primarily in the analysis of higher airborne asbestos concentrations which can be approximated adequately by a continuous distribution (USEPA 1985a,1986). A discrete version of the lognormal distribution was developed to compare the effect of the two distributions on the performance of the clearance procedure (Appendix B).

The probability of passing the clearance test assuming a discrete lognormal distribution was compared with that previously obtained assuming a negative binomial with corresponding mean and coefficient of variation (CV = standard deviation/ mean). The values of variables used in the simulation program are listed in Table 1.

TABLE 1. VARIABLES USED IN THE SIMULATION PROGRAM

Protocol Variables	Lognormal and Negative Binomial	Input/Output Test	Sampling Volume
effective filter area	855mm ²	855mm ²	855mm ²
area of one grid opening	0.0057mm ²	0.0057mm ²	0.0057mm ²
number of grids examined	10	10	24, 10, 4
volume of air collected	3,000L	3,000L	1,250L 3,000L 7,600L
number of inside samples	5	5	5
number of outside samples	5	5	5
number of blanks	3	0	3

Simulation Variables	
number of replications	500
k parameter of negative binomial*	1, 0.65, 0.4
coefficient of variation for lognormal	1.0, 1.25, 1.6
outside concentration	0.005, 0.02 fibers/cm ³
inside concentration	1x, 2x, 5x, 10x, 15x, 20x
blank contamination	17.5, 35, 70 fibers/mm ²

* The same value of k (negative binomial) or the coefficient of variation (lognormal) was used for inside, outside, and blank concentrations.

Tests for the Inside/Outside Comparison

The proposed rule requires the Z-test for comparing airborne asbestos concentrations inside the work site with concentrations outside the work site. The Z-test is a modification of the previously recommended t-test (Chesson et al 1985, USEPA 1985b,c). The Z-test uses a fixed value of 0.8 for the standard deviation, whereas the t-test uses a value estimated from the data. The Z-test was introduced to eliminate problems caused by the imprecision of a standard deviation estimated from a small number of clearance samples and to simplify calculations.

Two other inside/outside tests are considered - a test based on the Poisson distribution (Cox and Lewis 1966), and the Wilcoxon test (Sokal and Rohlf 1969) which does not assume a particular parametric distribution. The four tests are defined in Appendix C.

Although the tests are derived from arguments that assume various distributions for airborne asbestos concentrations, once the test has been specified it should be evaluated under a variety of conditions other than those for which it was derived. The true distribution of airborne asbestos concentrations in any particular situation is unknown. Therefore it is important that a statistical test used for regulatory purposes be robust to deviations from the assumptions on which it is based. For example, the Poisson test will perform well when the underlying distribution is Poisson. However, there is ample evidence that the Poisson distribution is an inadequate description of airborne asbestos concentrations (Javitz and Fowler 1981). Therefore it is essential to investigate its performance under other distributional assumptions.

The performance of the four tests was compared by evaluating their false positive and false negative error rates in a variety of situations assuming a negative binomial distribution for airborne asbestos concentrations. For this comparison the initial screening test and the blank contamination test were not included in the simulation. Five inside samples and five outside samples were generated and subjected to each of the four inside/outside tests.

Sampling Volumes

The proposed rule specifies maximum and minimum air volumes. A decrease in air volume must be accompanied by an increase in the area of filter examined (number of grid openings) to maintain an analytical sensitivity of 0.005 f/cm^3 or less. False positive and false negative rates were estimated for the maximum and minimum air volumes and compared to those estimated for a volume within the recommended range. The simulation variables are given

in Table 1. The full 3-step clearance procedure was used for this comparison.

Fiber Length and Aspect Ratio

The proposed rule defines an asbestos fiber as "a structure >0.5 micrometers in length with an aspect ratio (length to width) of 5 to 1 or greater and having substantially parallel sides." This definition differs from previous TEM protocols that specified no minimum length, and required an aspect ratio of 3 to 1 or greater. The possible effects of this new definition on the performance of the clearance procedure are discussed.

SECTION 5

RESULTS

UNDERLYING DISTRIBUTION

When a lognormal instead of a negative binomial distribution is assumed for the number of asbestos fibers counted on a filter the clearance procedure has a lower false negative error rate. (A complete listing of the results appears in Appendix D.) There is a reduction of approximately 10% in the probability of passing when indoor concentrations are between 5 and 10 times outside concentrations (Figures 3 and 4). When inside concentrations are either less than 5 times or more than 10 times outside, the difference between the two distributions is not as great. Figures 3 and 4 assume a coefficient of variation of 100%. The difference between the distributions is greater when the coefficient of variation is 160% (Figure 5).

The clearance procedure is expected to perform better when the underlying distribution is lognormal since the Z-test is based on a lognormal distribution. In the absence of convincing evidence that the lognormal is the "true" distribution of airborne asbestos concentrations it is conservative to use a negative binomial distribution to evaluate the performance of the clearance procedure. Of the two distributions, the negative binomial represents a "worse case" evaluation.

TESTS FOR THE INSIDE/OUTSIDE COMPARISON

The Z-test emerges as the test with the lowest false negative error rate while still maintaining a false positive error rate of less than 10%. Of the four tests considered, the Wilcoxon has the highest false negative error rate followed by the t-test, Z-test, and Poisson (Figures 6 and 7). The Poisson test has the highest false positive error rate. (The false positive rate can be read from Figures 6 and 7. It is one minus the probability of passing when inside concentration equals outside concentration.) When the outside concentration is 0.02 f/cm^3 and the coefficient of variation is approximately 1.0 ($k=1$) the false positive error rate is 22%. It increases to 26% when the coefficient of variation is approximately 1.6 ($k=0.4$). The Wilcoxon, t-test and Z-test all have false positive error rates of less than 10%.

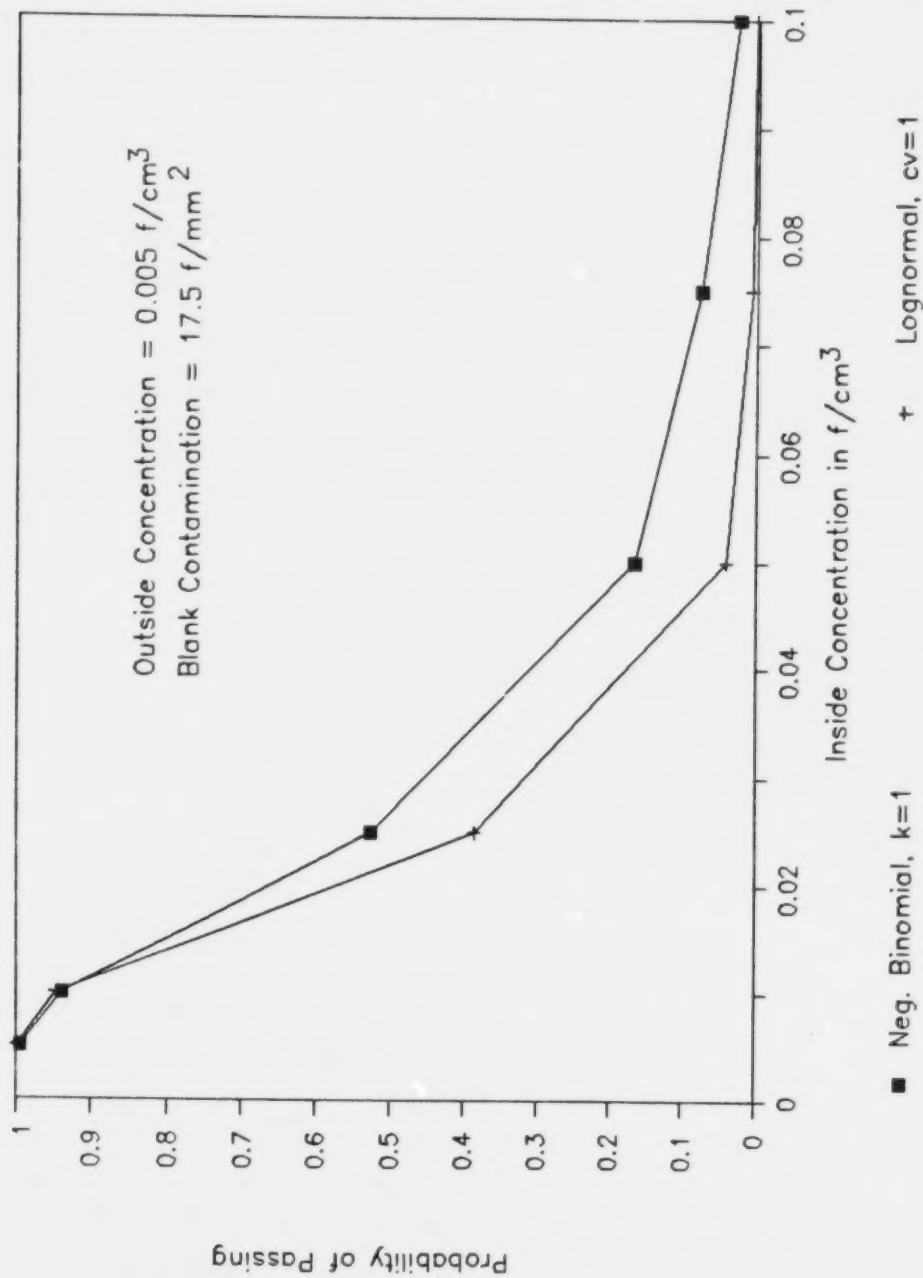


Figure 3: The effect of assuming a lognormal distribution instead of a negative binomial distribution for airborne asbestos concentrations when the outside concentration is 0.005 f/cm^3

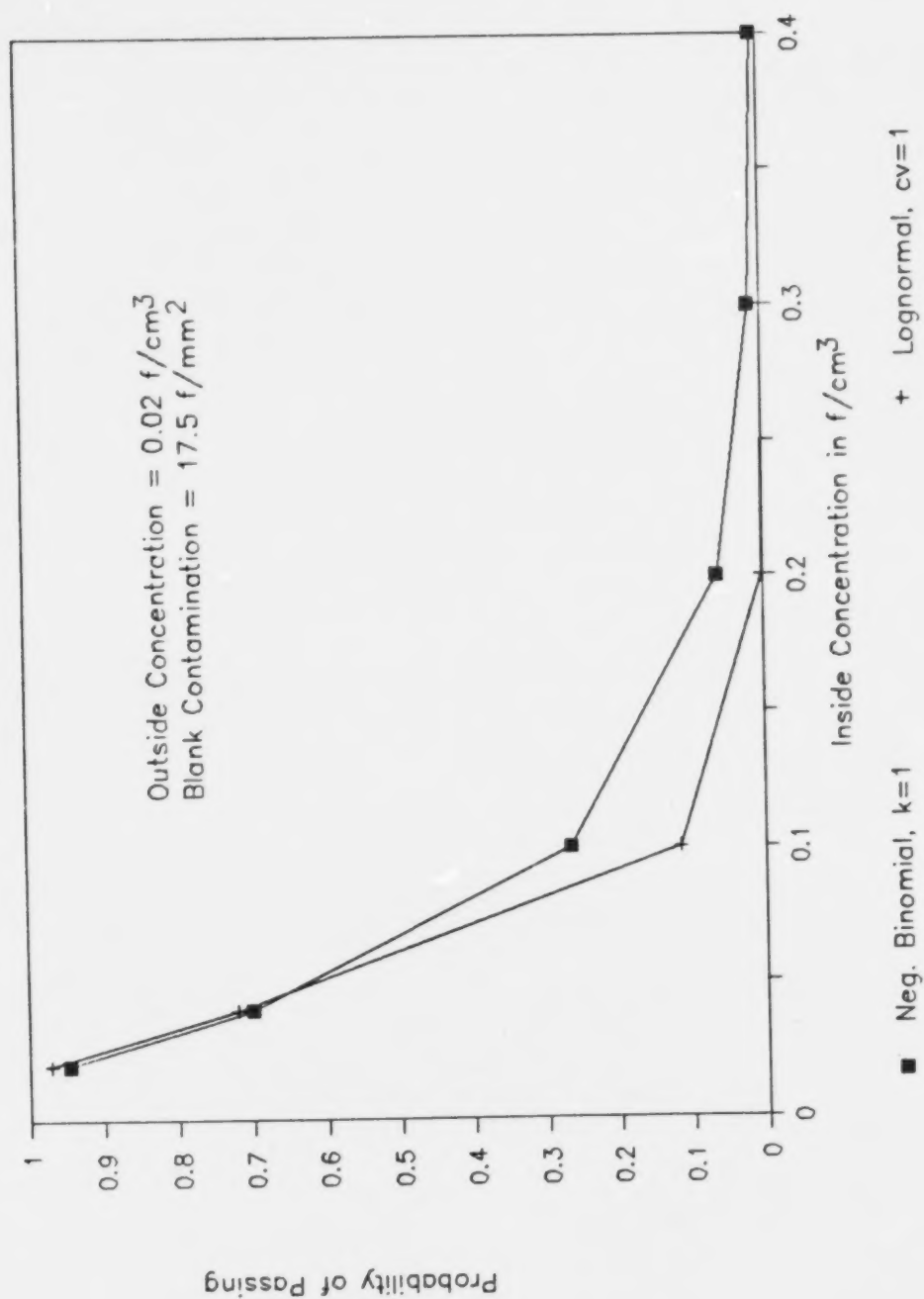


Figure 4: The effect of assuming a lognormal distribution instead of a negative binomial distribution for airborne asbestos concentrations when the outside concentration is 0.02 f/cm^3

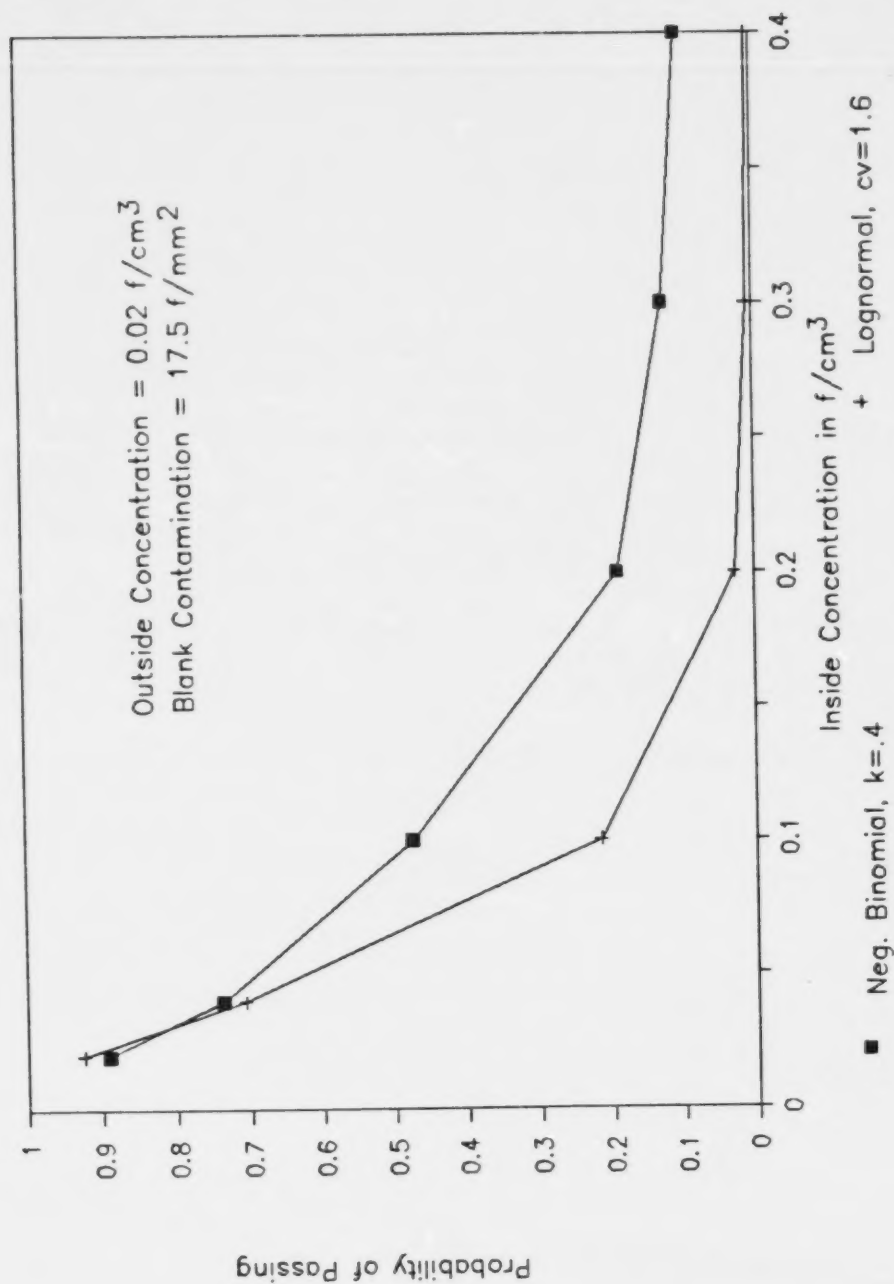


Figure 5: Increasing the coefficient of variation to 1.6 ($k = 0.4$) increases the difference between the false negative error rates for the lognormal and negative binomial distributions.

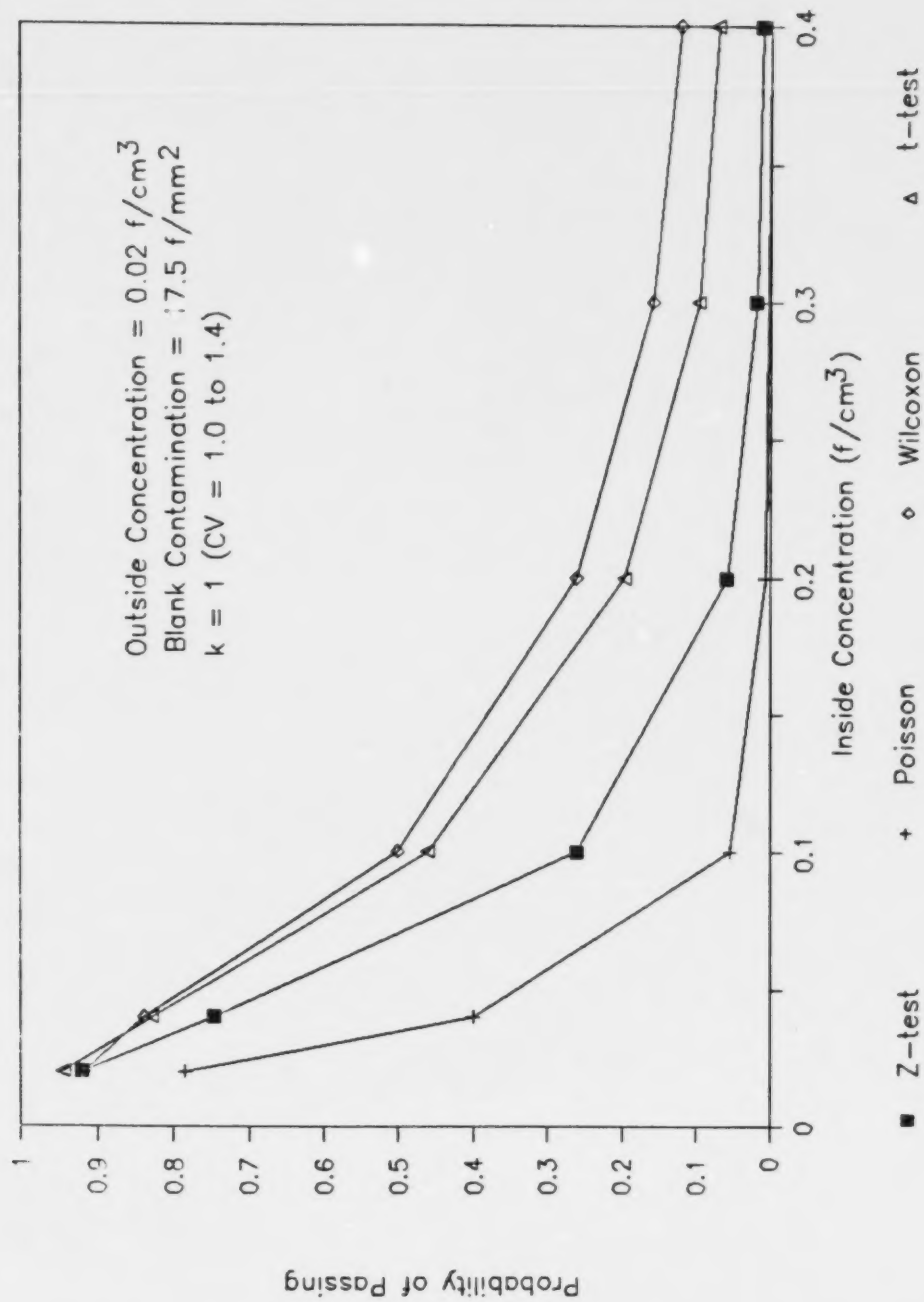


Figure 6: Comparison of inside/outside tests for $k = 1$.

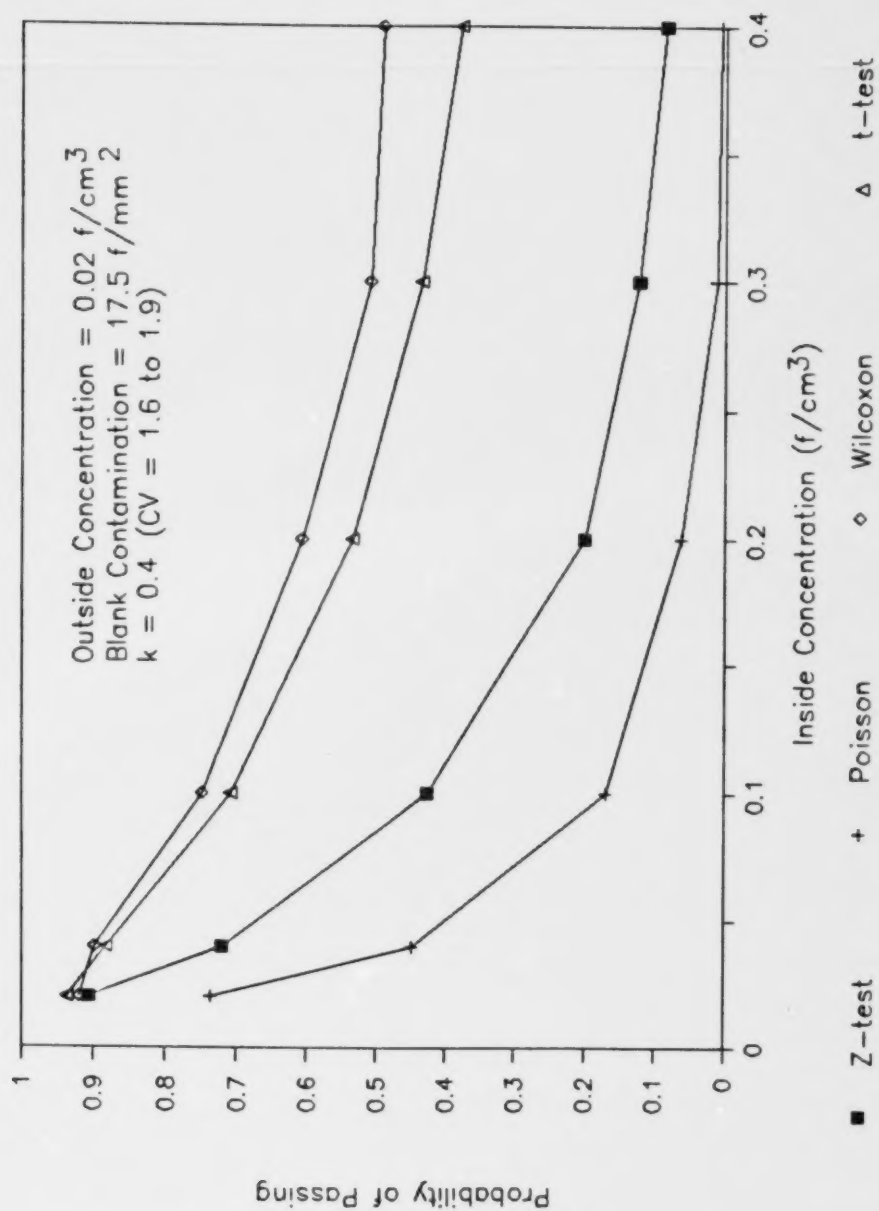


Figure 7: Comparison of inside/outside tests for $k = 0.4$.

The low false negative rate for the Poisson test is not surprising because the test is based on a coefficient of variation of less than 100%. (The variance of the Poisson distribution equals the mean.) When the coefficient of variation is larger, as it is for the negative binomial distribution, the probability of passing the Poisson test is reduced. The high false negative rate of the Wilcoxon test is also not surprising because the test uses only the ranks of the observations, not their values, and therefore tends to have lower statistical power, especially when sample sizes are small.

As the coefficient of variation increases from 1.0 (Figure 6) to 1.6 (Figure 7) the false negative error rates of the t-test and Wilcoxon test increase considerably. The t-test involves estimating the standard deviation from the data. Therefore, as the coefficient of variation increases, the estimated standard deviation also increases and the probability of passing the test increases. Correspondingly, the ranks of five inside measurements are less likely to be significantly different from the ranks of five outside measurements as the coefficient of variation increases, and the probability of passing the Wilcoxon test increases.

SAMPLING VOLUMES

The performance of the clearance test was evaluated using the maximum (7,600L), recommended (3,000L), and minimum (1,250L) volumes under the proposed rule. Results are listed in Appendix F. Figure 8 shows that decreasing the sampling volume increases the false negative error rate when the outside airborne asbestos concentration is 0.005 f/cm^3 . The effect is greatest where inside concentrations are between 5 and 10 times the outside concentrations. At these low concentrations there is a short-term cost advantage to collecting the minimum volume since there is an increased probability of passing the initial screening test. The possible short-term cost advantage is countered, however, by the cost of examining the additional grid openings required to achieve an analytical sensitivity of 0.005 f/cm^3 . When outdoor concentration is 0.02 f/cm^3 there is little effect of volume on the probability of passing the clearance test (Figure 9).

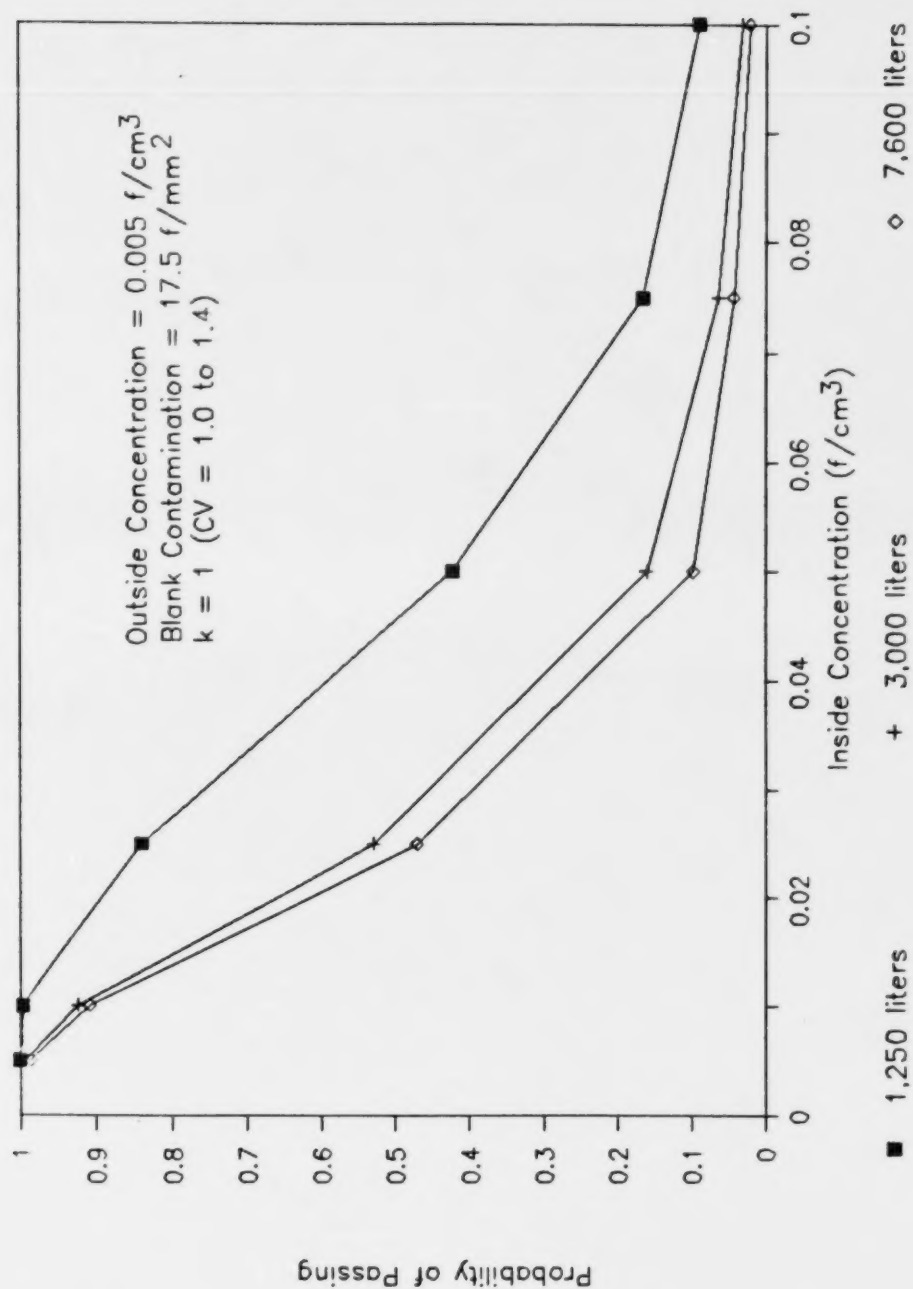


Figure 8: The effect of sampling volume when outside concentration is f/cm^3

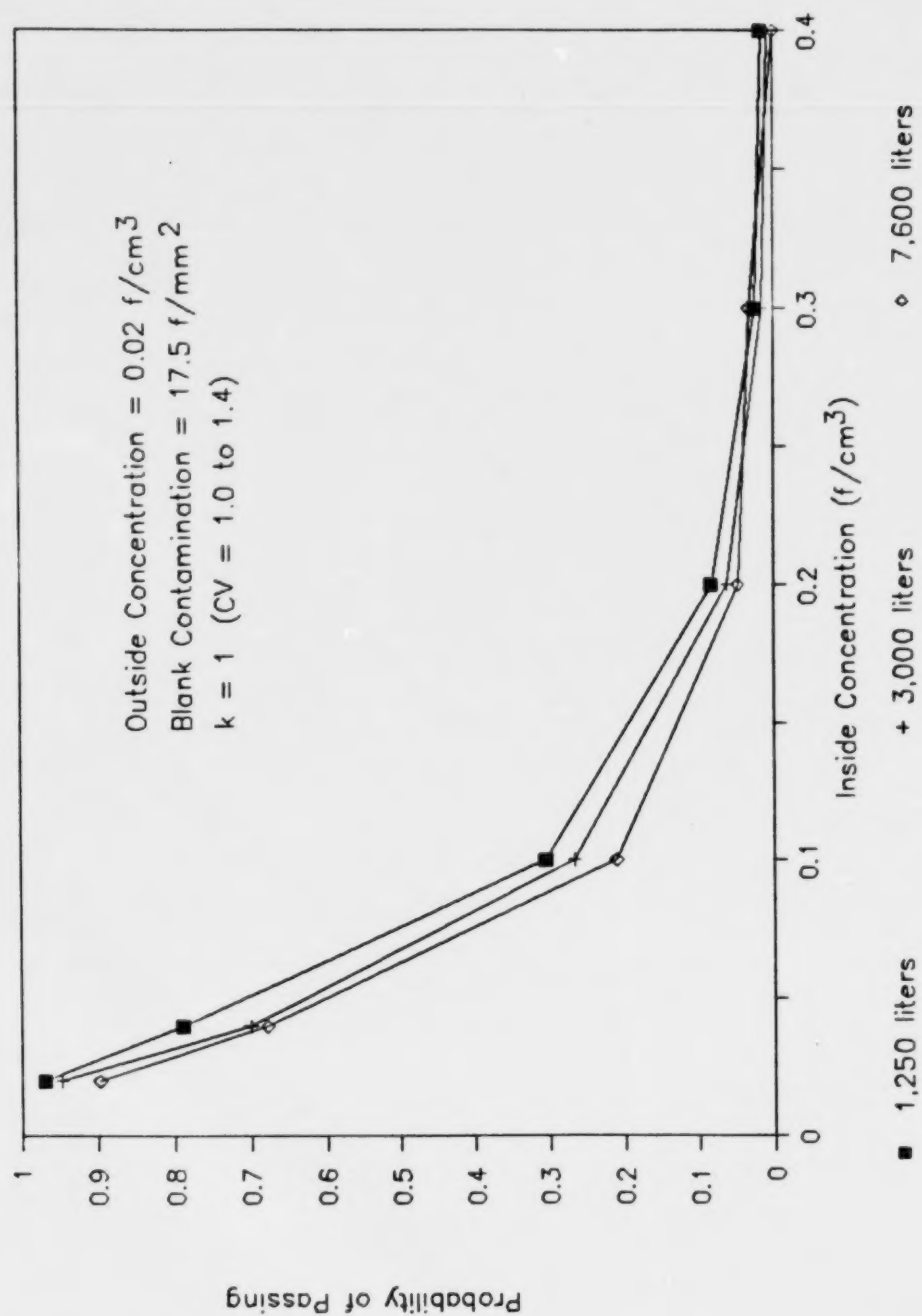


Figure 9: The effect of sampling when outside concentration is 0.02 f/cm^3

FIBER LENGTH AND ASPECT RATIO

The proposed rule defines fibers as having a minimum length of $0.5\mu\text{m}$ and an aspect ratio (length:width) of at least 5:1. Previously there was no minimum length and the minimum aspect ratio was 3:1. The change reduces the fiber concentrations reported, since some fibers previously included in the count will now be excluded. The change was justified on the basis of increased precision (less variability in the fiber counts).

Table 2 summarizes the effects on the false negative error rate of the clearance test. Increased precision will reduce the false negative error rate. The reduction in estimated airborne asbestos concentrations will increase the false negative error rate for the initial screening test and the blank contamination test. If the proportional reduction is the same for both inside and outside measurements (i.e., both sets of samples have the same distribution of fiber sizes) the performance of the Z-test will be unaffected. If the proportional reduction is greater for the outside samples (i.e., if outside samples have a larger proportion of their fibers less than $0.5\mu\text{m}$ long and with an aspect ratio of less than 5:1) the false negative error rate for the Z-test will be reduced.

Quantitative information on the magnitude of the competing effects is needed before the effect on the overall clearance test can be determined. Data on precision should be obtained from designed laboratory experiments involving replicate analyses of samples. Data on fiber size distributions can be obtained from TEM analyses of inside and outside samples. As it is likely that fiber size distributions vary from place to place, a wide range of samples will have to be examined before any general conclusions can be reached.

An alternative approach, which would complement the one above, is to use computer simulation to explore the sensitivity of the clearance test to changes in precision and fiber size distribution. This would lead to defining the range of circumstances over which effects of different magnitudes occur.

TABLE 2. THE EFFECT OF RESTRICTING FIBER LENGTH TO 0.5 μm AND ASPECT RATIO TO 5:1 OR GREATER ON THE FALSE NEGATIVE RATE OF THE CLEARANCE TEST

Possible Effect on TEM analysis	Effect on False Negative Error Rate of:			
	Initial Test	Blank Test	Z-test	Overall Test
Improved precision	reduced	reduced	reduced	reduced
Lower fiber concentration				
- same effect inside and out	increased	increased	no effect	increased
- greater effect inside than out	increased	increased	decreased	?

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APPENDIX A

FORMULAE FOR ANALYTICAL SENSITIVITY AND FIBER CONCENTRATIONS

Analytical sensitivity (f/cm^3) = $(1/a)(A/V)$

where A = effective area of filter (mm^2)
 a = area of filter examined (mm^2)
 = number of grid openings x area of 1 grid
 opening
 V = volume of air collected (cm^3).

Fiber concentration per square mm of filter (f/mm^2) = n/a

where n = number of fibers counted
 a = area of filter examined (mm^2).

Fiber concentration per cubic centimeter (f/cm^3) = $(n/a)(A/V)$

where n = number of fibers counted
 a = area of filter examined (mm^2)
 A = effective area of filter (mm^2)
 V = volume of air collected (cm^3).

APPENDIX B

DERIVATION OF A DISCRETE VERSION OF THE LOGNORMAL DISTRIBUTION

The objective is to derive a discrete random variable, W , with a distribution that approximates a lognormal distribution with mean m and coefficient of variation c .

Let X have a lognormal distribution with mean m and coefficient of variation c . Then $Y = \ln X$ is normally distributed with mean $\mu = \ln(m/\sqrt{1+c^2})$ and variance $\sigma^2 = \ln(c^2+1)$.

Define the discrete random variable, W , by

$$P(W=w) = \int_{w-0.5}^{w+0.5} f(x) dx$$

where $f(x)$ is the probability density function of X , i.e., the probability of W taking a particular value, w , is equal to the probability of the lognormal distribution taking a value between $w-0.5$ and $w+0.5$.

$$\begin{aligned} P(W=w) &= P(w-0.5 \leq X < w+0.5) \\ &= \begin{cases} \Phi((\ln(w+0.5)-\mu)/\sigma) & \text{for } w=0 \\ \Phi((\ln(w+0.5)-\mu)/\sigma) - \Phi((\ln(w-0.5)-\mu)/\sigma) & \text{for } w=1,2,3,\dots \end{cases} \end{aligned}$$

where Φ is the distribution function of the standard normal distribution.

APPENDIX C

DEFINITION OF THE FOUR TESTS PROPOSED TO COMPARE AIRBORNE
ASBESTOS CONCENTRATION INSIDE THE WORK SITE WITH THE
CONCENTRATION OUTSIDE THE WORK SITE

1. Z-test (52 FR 15820).

$$\text{Work site passes if } \frac{\bar{Y}_I - \bar{Y}_0}{0.8\sqrt{(1/n_I + 1/n_0)}} \leq 1.65,$$

where $\bar{Y}_I$ is the mean of the log (to the base e) concentrations inside the work site, $\bar{Y}_0$ is the mean of the log concentrations outside the work site, n_I is the number of samples inside the work site, and n_0 the number of samples outside the work site. Estimated airborne asbestos concentrations of zero are set to the analytical sensitivity before taking logs.

2. Poisson (Cox and Lewis 1966)

$$\text{Work site passes if } \sum_{x=0}^{n_0} \frac{n_t}{x} \frac{1}{2} n_t \geq 0.05$$

where n_0 is the total number of fibers counted on the outside filters n_I is the total number of fibers counted on the inside filters $n_t = n_0 + n_I$.

For values of $n > 50$ the normal approximation to this test is used:

$$\text{the work site passes if } \frac{n_0 - n_t/2 - 1/2}{\sqrt{(n_t/4)}} \leq 1.65$$

3. Wilcoxon (Sokal and Rohlf 1969)

The n_t observations are ranked together from low to high.

Average ranks are given to tied observations, including zero observations.

Let $U = R_0 - n_0 (n_0 + 1)/2$ where R_0 is the sum of the ranks of the outside samples.

Then the work site passes if U_S is greater than a critical value depending on the number of samples. For $n_I = n_O = 5$ the work site passes if $R_0 > 19$.

4. t-test (USEPA 1985b,c)

The work site passes if
$$\frac{\bar{Y}_I - \bar{Y}_O}{S \sqrt{(1/n_I + 1/n_O)}} < t_\alpha$$

where $S^2 = [\sum_i (y_{Ii} - \bar{y}_I)^2 + \sum_i (y_{Oi} - \bar{y}_O)^2] / (n_I + n_O - 2)$,

and the remaining notation is the same as for the Z-test.

Estimated airborne asbestos concentrations of zero are set to the analytical sensitivity before taking logs.

For $n_I = n_O = 5$, $t_\alpha = 1.86$.

APPENDIX D

COMPARISON OF LOGNORMAL AND NEGATIVE BINOMIAL DISTRIBUTIONS

TABLE D-1. PROBABILITY OF PASSING THE THREE-STEP CLEARANCE TEST
WHEN THE UNDERLYING DISTRIBUTION IS LOGNORMAL.

Outside Concentration = 0.005 f/cm^3

Blank Contamination Level

Inside Conc	17.5 f/mm ²			35 f/mm ²			70 f/mm ²		
	cv=1	cv=1.25	cv=1.6	cv=1	cv=1.25	cv=1.6	cv=1	cv=1.25	cv=1.6
0.005	1.00	0.99	0.99	0.98	0.98	0.96	0.70	0.73	0.72
0.010	0.95	0.94	0.91	0.89	0.86	0.85	0.58	0.62	0.63
0.025	0.38	0.42	0.52	0.44	0.52	0.53	0.41	0.42	0.41
0.050	0.04	0.07	0.15	0.10	0.16	0.19	0.16	0.20	0.21
0.075	0.01	0.02	0.05	0.03	0.05	0.10	0.06	0.10	0.13
0.100	0.00	0.00	0.01	0.01	0.02	0.05	0.03	0.05	0.09

Outside Concentration = 0.02 f/cm^3

Blank Contamination Level

Inside Conc	17.5 f/mm ²			35 f/mm ²			70 f/mm ²		
	cv=1	cv=1.25	cv=1.6	cv=1	cv=1.25	cv=1.6	cv=1	cv=1.25	cv=1.6
0.020	0.97	0.94	0.92	0.90	0.90	0.87	0.58	0.56	0.64
0.040	0.72	0.68	0.71	0.78	0.71	0.65	0.51	0.49	0.52
0.100	0.11	0.16	0.21	0.16	0.20	0.24	0.18	0.20	0.25
0.200	0.00	0.02	0.03	0.01	0.03	0.05	0.02	0.03	0.07
0.300	0.00	0.00	0.01	0.00	0.00	0.01	0.00	0.01	0.04
0.400	0.00	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.01

TABLE D-2. PROBABILITY OF PASSING THE THREE-STEP CLEARANCE TEST WHEN THE UNDERLYING DISTRIBUTION IS NEGATIVE BINOMIAL (FROM CHESSON AND PRICE 1987).

Outside Concentration = 0.005 f/cm^3

Blank Contamination Level									
Inside Conc	17.5 f/mm ²			35 f/mm ²			70 f/mm ²		
	k=1	k=.65	k=.4	k=1	k=.65	k=.4	k=1	k=.65	k=.4
0.005	0.99	0.98	0.97	0.95	0.94	0.91	0.64	0.64	0.72
0.01	0.94	0.90	0.90	0.85	0.83	0.81	0.51	0.55	0.61
0.03	0.52	0.58	0.68	0.60	0.60	0.58	0.35	0.42	0.47
0.05	0.17	0.28	0.40	0.21	0.30	0.41	0.23	0.26	0.35
0.08	0.08	0.13	0.27	0.09	0.16	0.25	0.11	0.16	0.25
0.100	0.03	0.09	0.19	0.05	0.11	0.18	0.09	0.14	0.17

Outside Concentration = 0.02 f/cm^3

Blank Contamination Level									
Inside Conc	17.5 f/mm ²			35 f/mm ²			70 f/mm ²		
	k=1	k=.65	k=.4	k=1	k=.65	k=.4	k=1	k=.65	k=.4
0.020	0.95	0.91	0.89	0.87	0.81	0.79	0.57	0.54	0.58
0.040	0.70	0.77	0.74	0.70	0.66	0.67	0.47	0.43	0.50
0.100	0.27	0.32	0.47	0.28	0.34	0.38	0.21	0.27	0.33
0.200	0.06	0.12	0.19	0.06	0.11	0.20	0.06	0.12	0.21
0.300	0.02	0.08	0.12	0.02	0.07	0.17	0.01	0.06	0.10
0.400	0.01	0.04	0.10	0.01	0.04	0.11	0.01	0.04	0.07

APPENDIX E

PROBABILITY OF PASSING DIFFERENT FORMS OF THE INSIDE/OUTSIDE COMPARISON TEST

TABLE E-1.

Outside Concentration = 0.005 f/cm^3

Blank contamination = 17.5 f/mm^2

Inside Conc	k=1				k=.65				k=.4			
	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t
0.005	0.99	0.85	0.94	0.96	0.97	0.80	0.94	0.95	0.96	0.78	0.93	0.95
0.010	0.88	0.63	0.88	0.87	0.88	0.60	0.91	0.87	0.86	0.61	0.87	0.89
0.025	0.48	0.19	0.62	0.55	0.55	0.23	0.71	0.64	0.64	0.30	0.82	0.80
0.050	0.17	0.04	0.39	0.30	0.28	0.06	0.56	0.47	0.38	0.12	0.64	0.55
0.075	0.06	0.00	0.25	0.18	0.11	0.02	0.38	0.29	0.24	0.07	0.58	0.51
0.100	0.02	0.00	0.19	0.11	0.06	0.01	0.34	0.23	0.19	0.04	0.53	0.44

Outside Concentration = 0.02 f/cm^3

Blank contamination level = 17.5 f/mm^2

Inside Conc	k=1				k=.65				k=.4			
	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t
0.020	0.92	0.78	0.92	0.94	0.93	0.79	0.94	0.96	0.91	0.74	0.92	0.94
0.040	0.75	0.40	0.84	0.83	0.74	0.44	0.85	0.84	0.72	0.45	0.90	0.88
0.100	0.26	0.05	0.50	0.46	0.33	0.12	0.62	0.59	0.43	0.17	0.75	0.71
0.200	0.06	0.01	0.26	0.20	0.13	0.03	0.43	0.36	0.20	0.06	0.61	0.53
0.300	0.02	0.00	0.16	0.10	0.05	0.00	0.31	0.25	0.12	0.01	0.51	0.43
0.400	0.01	0.00	0.12	0.07	0.03	0.00	0.28	0.18	0.08	0.01	0.49	0.38

TABLE E-1 (CTD)

Outside concentration = 0.005 f/cm^3 Blank contamination level = 35 f/mm^2

Inside Conc.	$k=1$				$k=.65$				$k=.4$			
	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t
0.005	0.95	0.82	0.92	0.95	0.93	0.79	0.90	0.94	0.92	0.75	0.91	0.93
0.010	0.88	0.65	0.88	0.89	0.89	0.65	0.91	0.91	0.87	0.60	0.89	0.90
0.030	0.57	0.28	0.70	0.66	0.62	0.33	0.76	0.72	0.63	0.32	0.83	0.80
0.050	0.23	0.07	0.43	0.37	0.28	0.10	0.56	0.48	0.42	0.16	0.72	0.65
0.080	0.13	0.02	0.30	0.26	0.19	0.05	0.47	0.40	0.29	0.09	0.64	0.56
0.100	0.04	0.00	0.20	0.13	0.11	0.01	0.40	0.30	0.23	0.06	0.59	0.52

Outside concentration = 0.02 f/cm^3 Blank contamination level = 35 f/mm^2

Inside Conc.	$k=1$				$k=.65$				$k=.4$			
	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t
0.020	0.93	0.78	0.92	0.95	0.90	0.73	0.88	0.93	0.87	0.71	0.94	0.95
0.040	0.74	0.45	0.85	0.81	0.76	0.48	0.88	0.87	0.72	0.46	0.90	0.89
0.100	0.30	0.08	0.54	0.48	0.33	0.10	0.64	0.58	0.42	0.15	0.77	0.71
0.200	0.05	0.00	0.26	0.20	0.13	0.02	0.42	0.37	0.29	0.09	0.65	0.60
0.300	0.02	0.00	0.16	0.10	0.08	0.01	0.35	0.27	0.17	0.03	0.56	0.49
0.400	0.01	0.00	0.12	0.06	0.04	0.00	0.28	0.21	0.10	0.01	0.46	0.35

TABLE E-1 (CTD)

Outside concentration = 0.005 f/cm^3 Blank contamination level = 70 f/mm^2

Inside Conc.	k=1				k=.65				k=.4			
	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t
0.005	0.92	0.78	0.94	0.94	0.91	0.76	0.93	0.95	0.91	0.73	0.93	0.96
0.010	0.88	0.71	0.90	0.90	0.85	0.65	0.92	0.93	0.84	0.66	0.92	0.93
0.030	0.62	0.37	0.77	0.73	0.64	0.43	0.80	0.79	0.73	0.45	0.88	0.87
0.050	0.36	0.13	0.56	0.49	0.42	0.19	0.66	0.61	0.47	0.25	0.78	0.75
0.080	0.19	0.04	0.37	0.32	0.27	0.07	0.53	0.48	0.34	0.14	0.65	0.59
0.100	0.15	0.02	0.32	0.28	0.21	0.06	0.51	0.46	0.27	0.11	0.59	0.56

Outside concentration = 0.02 f/cm^3 Blank contamination level = 70 f/mm^2

Inside Conc.	k=1				k=.65				k=.4			
	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t	Z	Poisson	Wilk	t
0.020	0.94	0.79	0.93	0.96	0.90	0.75	0.92	0.95	0.88	0.68	0.92	0.95
0.040	0.79	0.51	0.86	0.83	0.76	0.45	0.86	0.87	0.78	0.49	0.92	0.92
0.100	0.35	0.08	0.52	0.46	0.45	0.15	0.72	0.67	0.47	0.20	0.76	0.73
0.200	0.11	0.01	0.26	0.22	0.18	0.02	0.47	0.40	0.30	0.06	0.67	0.62
0.300	0.03	0.00	0.18	0.13	0.09	0.01	0.33	0.28	0.18	0.03	0.54	0.49
0.400	0.01	0.00	0.12	0.08	0.05	0.01	0.29	0.24	0.16	0.03	0.50	0.46

APPENDIX F

PROBABILITY OF PASSING THE THREE-STEP CLEARANCE PROCEDURE WITH
THE MINIMUM, RECOMMENDED, AND MAXIMUM AIR VOLUMES PERMITTED UNDER
THE PROPOSED RULE

Outside Concentration = 0.005 f/cm^3

Blank contamination level									
	17.5 f/mi ²			35 f/mi ²			70 f/mi ²		
	1250L	3000L	7600L	1250L	3000L	7600L	1250L	3000L	7600L
Inside Conc									
0.005	1.00	0.99	0.99	0.96	0.95	0.91	0.73	0.70	0.60
0.010	1.00	0.92	0.91	0.94	0.85	0.79	0.64	0.55	0.50
0.025	0.84	0.53	0.47	0.71	0.53	0.39	0.48	0.39	0.30
0.050	0.42	0.16	0.10	0.44	0.19	0.14	0.33	0.19	0.11
0.075	0.17	0.06	0.04	0.23	0.08	0.06	0.26	0.11	0.05
0.100	0.09	0.03	0.02	0.18	0.05	0.04	0.17	0.06	0.02

Outside Concentration = 0.02 f/cm^3

Blank contamination level									
	17.5 f/mi ²			35 f/mi ²			70 f/mi ²		
	1250L	3000L	7600L	1250L	3000L	7600L	1250L	3000L	7600L
Inside Conc									
0.020	0.97	0.95	0.90	0.90	0.87	0.80	0.64	0.57	0.46
0.040	0.79	0.70	0.68	0.76	0.70	0.61	0.51	0.47	0.41
0.100	0.30	0.27	0.21	0.34	0.28	0.19	0.27	0.21	0.17
0.200	0.08	0.06	0.05	0.11	0.06	0.03	0.13	0.06	0.03
0.300	0.02	0.02	0.03	0.05	0.02	0.01	0.05	0.01	0.01
0.400	0.02	0.01	0.00	0.01	0.01	0.01	0.03	0.01	0.00